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EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,969

Applicant(s)

GARRITY ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 66-84 is/are pending in the application.
- 4a) Of the above claim(s) 42, 43 and 66-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 and 66-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicants' provisional election of Group I – claims 1-41 with traverse is acknowledged. (Paper#11 filed 5/6/03). Applicant does not traverse the Restriction Requirement on the grounds of lack of patentable distinctness. The traversal on the ground(s) "that the examiner has not shown that a serious burden would be required to examine all of the claims", is not found convincing.

This is not found persuasive because MPEP § 808.02 recites:

Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

2. In the instant case, (A) -The Restriction Requirement under 35 U.S.C. § 121 in Paper #10 established distinctness of the inventions and separate classification thereof:

(B) The inventions of Groups I, II, V, VI, and VII would require a separate status in the art when they are classified together; the invention as a whole is drawn to 25-OH-D detection (Vitamin D Assay). Such inventions are classified in 436, subclass 63 for example.

(C) With respect to a different field of search – Because these inventions are distinct and have acquired separate status in the art as shown by their different classification, recognized divergent subject matter and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper.

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Please note that the classifications in the restriction are illustrative only and do **not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes published foreign patents and applications as well as literature search.

3. Further, the combination of Groups I, II, V, VI, and VII (claims 1-43 and 66-84) for examination on the merits is deemed incorrect. The merging of these groups would combine patentably distinct inventions.

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

4. Currently, claims 1-43 and 66-84 are subject to Restriction and Election Requirement. Claims 42-43 and 66-84 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 1-41 are currently pending and under examination.

Priority

5. The instant application does not claim priority or benefits to an earlier application.

Drawings

6. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. See Table I. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

8. The information disclosure statements filed 3/22/01-Paper#5, 6/4/01-Paper#6, and 6/23/03-Paper#12 have been considered as to the merits prior to first action.

Oath/Declaration

9. A new oath or declaration is required because:

- A. It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.
- B. Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.
- C. It does not identify the citizenship of each inventor.

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The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. The use of the trademarks has been noted in this application. (i.e. Sephadex -page 26, Tween -page 10, Triton -page 10). All trademarks in the disclosure should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

12. Content of Specification – The brief description of the drawing for Table I is not included in the disclosure. Please add.

- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f).
A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "facilitates" in claim 1 is a relative term which renders the claim indefinite. The term "facilitates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear if the composition will actually produce the desired effect or is in some other way related to the desired effect. For example, will the releasing composition release the vitamin D component or not? It is suggested that the term "facilitates" be removed from the claim for clarity.

B. Claim 1 is vague and indefinite because it is unclear as to how the "vitamin D component binding-protein complex" will necessarily exist in the test sample a priori to the addition of the releasing composition. In other words the kit of claim 1 does not include a binding-protein reagent to bind the vitamin D of interest. The kit requires the vitamin D component to be bound in order for it to be released by the releasing composition. In order to obviate this rejection a vitamin D binding protein component should be added to claim 1.

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C. Claim 2 provides for the use of the kit in claim 1. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The term “useful” should be omitted.

D. Claim 3 is ambiguous in utilizing the phrase “mixtures thereof”. The recited claim is unclear because it is not known if the composition contains mixtures of the recited fluid (milk and whole blood together) or any mixture in combination with the recited fluid (milk and alcohol). The meaning of mixture thereof is not defined in the disclosure, as such the nature, direction, or degree of said fluid composition is not clear. Please remove “mixture thereof” from the claim.

E. In claim 12 the phrase “substantially free” is indefinite because “substantially” is a broad term lacking definitiveness. *In re Nehrenberg* (CCPA) 126 USPQ 383. The term implies that something less than exact correspondence is required. Therefore it is not clear as to what Applicant will consider “substantially free” of an organic solvent.

F. In claim 15 the use of “randomly” methylated is not clear. Is it applicant’s intent to mean any composition including methyl. Please correct/explain.

G. The use of “including” in claim 19 is unclear because it is not certain if “sodium salicylate” is intended to be recited as a limitation or a mere example of possible components. Please correct.

H. The trademarks in claim 21 render the claim indefinite. The use of the trademarks has been noted in this application. (Tween and Triton). All trademarks in the disclosure should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Appropriate correction required.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-6, 12-18, 20-22, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076.

Kobayashi et al. teach reagents for measuring 25-hydroxy vitamin D₃ [25(OH)D₃] with solubilizing agents (releasing compositions). 25-hydroxy vitamin D₃ [25(OH)D₃] in serum or plasma is taught to be the major circulation metabolite of vitamin D.

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Kobayashi et al. also teach that the addition of the proper solubilizing agent to vitamin D assay buffer is essential to the development of a sensitive and reproducible assay system. See abstract. Various solubilizing agents at different concentrations were tested as to their effects on the antigen-antibody reaction. These solubilizing agents (releasing compositions) includes aqueous bases such as BSA, OVA. Further employed was a PEG and Tween 20 (surfactant) combination. Cyclodextrin (CDs) were also added at various concentrations (i.e. 2,6,-di-*O*-methyl)- β -cyclodextrin – Me- β -CD). See page 84-85 and Table I. The mixtures produce homogenous reaction which are subsequently assayed via a radio immunoassay. Particularly, the vitamin D component was measured by competitive binding assays (CPBA) employing serum vitamin D binding protein (DBP) and immobilized goat anti-rabbit immunoglobulin (DASP beads). With respect to the variation/change in solubilizing compound concentration, such modifications are viewed as mere optimization and does not impart patentability unless the recited ranges are critical, i.e. they produce a new and unexpected result. *In re Aller et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233.

Portions of ingredients, to impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. *In re Fields* (CCPA 1962) 304 F2d 691, 134 USPQ 242. The proportions must be critical, i.e., they must produce difference in kind rather than degree. *In re Touvay et al.* (CCPA 1958) 264 F2d 901, 121 USOQ 265.

Kobayashi et al. differ from the instant invention in not specifically teaching the assay reagents as a kit.

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However, Incstar Corporation provide a kit format to measure 25-hydroxy vitamin D₃ [25(OH)D₃]. The components include an extraction reagent (solubilizing reagent/releasing composition) and detection reagents.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the reagents used in the vitamin D detection assay as taught by Kobayashi et al. and format them into a kit because the Incstar Corporation provide support for such kit configurations in other words kit formats are convenient.

Further, one can enhance sensitivity of a method by providing reagents as a kit. The reagents in a kit are available in pre measured amounts which eliminates the variability that can occur when performing the assay.

One of ordinary skill in the art would have been motivated to manufacture kits comprising the reagents known in the prior art in order to take advantage of the economic benefits.

II. Claims 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 and in further view of Atkinson et al. (WO 89/05356).

Please see Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 as set forth above.

Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 differ from the instant invention in not specifically teaching a kit reagent comprising metal salicylate, like sodium salicylate.

Atkinson et al. disclose this limitation. The reference teaches methods and kits to assay salicylates or reduced pyridine nucleotides. See abstract. In one embodiment the kit contains an enzyme reagent comprising sodium salicylate. See example 3 on page 18 and example 5 on page 20.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to include the metal salicylate, like sodium salicylate of Atkinson et al. in the kit reagents as taught by Kobayashi et al. in view of the Incstar Corporation because Atkinson et al. taught that salicylate compositions are important in drug evaluation of biological fluids (page 1 lines 7-12) and the salicylate compounds are useful as color indicators (page 1 line 14-22).

III. Claims 7, 25-27 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 and in further view of DeLuca et al. (US Patent #5,064,770).

Please see Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 as set forth above.

Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 do not teach the utility of a host component binding partner complex (double antibody) kit configurations.

DeLuca et al. teach methods and kits for assay 1,25 dihydroxy vitamin D receptor protein (another vitamin D metabolite/component). The kits comprise a first radioactively labeled antibody capable of binding to a first epitope of the vitamin receptor D protein (partner component) and a second antibody capable of binding to a second epitope of the vitamin D receptor(detecting composition). Column 2 lines 33-65 and claims 4-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an additional binding composition specific for the host (vitamin D) as taught by DeLuca et al. in the kit of Kobayashi et al. in view of the Instruction Manual of Incstar Corporation because DeLuca et al. disclosed that his assay was sensitive, reproducible, easy to use, and useful in connection with crude samples from mammalian sources. Column 2 lines 6-10. DeLuca et al. teach the anchoring of vitamin D via a partner component helps to stabilize the receptor, eliminated excess unbound reagent, and prevents denaturing. Column 2 lines 44-60.

IV. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076.

Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 differ from the instant invention in not specifically teaching the NaOH and KOH as aqueous base components.

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However, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to substitute the known basic compositions (NaOH or KOH) and employ them in the kit of Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 because the mere substitution of one equivalent for another (aqueous base solutions) is not an act of invention. *Butler Bros. v. Pratt* (CCPA 8) 253 F 654, 656. Persons of reasonable skill in the art would have recognized the equivalency. This is supported by the Aldrich list of Volumetric Solutions which lists known aqueous base solutions.

V. Claims 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (Clinica Chimica Acta, 209, 1992, page 83-88) in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 and in further view of DeLuca et al. (US Patent #5,064,770) as applied to claims 7, 25-27 and 38-40 above, and further in view of Nargessi et al. (US Patent #5,770,176).

Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 and in further view of DeLuca et al. are set forth above.

Kobayashi et al. in view of the Instruction Manual of Incstar Corporation, 1992 – Cat#26076 and in further view of DeLuca et al. differ from the instant invention in not teaching acridinium as a label and magnetic particles as a separator component.

However Nargessi et al. disclose methods and kits involved in the measurement of receptors. See abstract and figure 1. The receptors include Vitamin D. See column 8. lines 23-33. The assay and kits teach the utility of magnetic particles (column 19 lines 9-11) and acridinium (Column 20 lines 27-28).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take employ magnetic particles and acridinium labels as taught by Nargessi in the vitamin D detection kit of Kobayashi et al. in view the Incstar Corporation and in further view of DeLuca et al. because Nargessi taught that magnetic particles were particularly preferable in automated procedures. Column 19 line 9-11. While the reagents could be labeled in any manner directly or indirectly as long a visible signal was generated. Column 19 lines 60-64. Preferred labels were luminescent signals (such as acridinium) because simplicity, analytical sensitivity, further allowing for the measurement of small amounts of analytes. Column 10 lines 15-28.

Allowable Subject Matter

15. A kit comprising at least three compositions (NaOH, cyclodextrin, and sodium salicylate) appears to be allowable over the prior art of record. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. For reasons aforementioned, no claims are allowed.

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17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook

CM1-7B17

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7/11/03



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07/14/03